European Environmental Bureau (EEB), CHEM Trust and Health and Environment Alliance (HEAL) comments on the update of REACH information requirements for Ecotoxicological information and Toxicokinetics/ADME.

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Introduction

The standard information requirements for REACH registration dossiers are key to the identification of hazardous chemicals under the REACH and CLP regulation. Updating these requirements should enable an effective identification of critical hazards at all tonnage levels, including for the new CLP hazard classes regarding persistent chemicals and endocrine disruptors, as recognised in the CSS. This document presents the joint NGO comments on the Commission proposals (CASG-IR-ED/06/2025 & CASG-IR-ED/07/2025) discussed at the REACH and CLP Competent Authorities subgroups meeting on 24 March 2025. It addresses the proposed amendments for information requirements regarding the environmental safety assessment and toxicokinetics.

We have not yet received the full legal proposal for standard information requirements which makes it difficult to provide detailed suggestions when not having the full picture. Therefore, our comments are based on the documents sent out, the presentations given by the Commission and the comments made at the meeting 24 March 2025.

Comments

Environmental safety assessment [Document CASG-IR-ED/06/2025]

Annex VIII - Section 9.1.3 Short-term aquatic toxicity

Commission proposal: The Commission proposed to replace short term fish toxicity testing by the introduction of two alternative assays, noting that information from one of these assays would be sufficient to meet the standard information requirements:

- In vitro cytotoxicity testing in fish cell line (OECD TG 249)
- Fish embryo toxicity testing (OECD TG 236)

NGO comments: We generally support the proposal to replace short-term fish toxicity tests, if relevant, standardised, and validated alternative assays with a well-defined applicability domain are available. However, metabolism remains a key concern. Current assays may not detect toxic metabolites, potentially leading to an underestimation of toxicity. This issue requires further consideration.
In addition, while the Commission suggests that either test may be sufficient to fulfil the REACH information requirements, we note that the OECD has advised against using TG 249 as stand-alone evidence. Further assessment and specific guidance on its applicability domain will be necessary. Therefore, we suggest that both tests be made mandatory as the minimum information requirement at Annex VIII.

Annex VIII - Section 9.3.1 Adsorption/desorption screening

Commission proposal: Amendment of column 2 to indicate that adsorption/desorption assessment is required if the chemical safety assessment indicates that additional information on mobility is required to assess PMT or vPvM properties of the substance. In addition, the REACH Annexes will include the obligation to assess PMT/vPvM properties in analogy to PBT/vPvBs.

NGO comments: We strongly support aligning the PMT/vPvM assessment with the PBT/vPvB framework throughout REACH, including updating the REACH Annexes to implement the PMT/vPvM assessment in analogy to PBT/vPvB assessment and to enable classification under the CLP regulation. The assessment of these persistent chemicals is urgently needed to ensure their identification and prevent worldwide and long-lasting pollution of drinking water resources.
In addition, information on sorption is needed for the environmental risk assessment. Therefore, an update of the information requirements regarding sorption and the mobility assessment is urgently needed. However, we would like to request that the Commission reconsiders the proposed text. While aligning the mobility (M) assessment with persistence (P) and bioaccumulation (B) screening is logical, there is a key difference in available screening-level information for P and B versus the information available for M: screening level information is already required under Annex VII for P (ready biodegradation test) and B (log Kow). In contrast, there is currently no equivalent screening information requirement for M under Annex VII.

Therefore, we propose to:

- Include screening level information on adsorption/desorption in Annex VII, including an in-silico determination of Koc.
- Add a dissociation constant as standard information requirement to Annex VII, relevant for the assessment of bioaccumulation and environmental mobility.
- Introduce a sorption study (OECD TG 106) as a standard information requirement at Annex VIII. This test will serve both the environmental risk assessment and PMT/vPvM assessment.
- Remove the existing log Kow based waiver from Annex VIII: The existing waiver for adsorption/desorption testing based on low log Kow should be deleted, as it counters the mobility assessment, as part of the PMT/vPvM identification.

- Merge Annex VII and Annex VIII requirements to enable screening level assessments for all critical hazards and chemical safety assessments at low tonnage level as well.

Annex IX - Section 9.1.6 Long-term toxicity testing on fish

Commission proposal: Allow waiving of the default long-term toxicity fish study in case results from one out of four other fish toxicity studies are already available. Add text to column 2, indicating need for fish sexual development test in case of evidence of endocrine disrupting properties.

NGO comments: Although we are generally in agreement with the proposed waiver, we have the following suggestions and observations:

- We agree with the suggestion made at the meeting, that in case of evidence of ED effects, the FSDT may not be the best choice in all cases.
- Furthermore, we would not support the use of risk-based waivers for long term fish testing, (as proposed by some parties during the meeting), due to the lack of adequate information on uses and exposure during the life cycle, and earlier Board of Appeal decision.
- Finally, we support the suggestion made at the meeting to amend the waiver in Annex IX, section 9.1 Column 2, to include the investigation of relevant transformation and degradation products on aquatic organisms. This amendment is needed to align with the waivers for long term toxicity testing for soil and sediment organisms.

Annex IX - Section 9.3.2 Bioaccumulation in aquatic species

Commission proposal: require bioconcentration testing preferably in invertebrates instead of fish.

NGO comments: We generally support the replacement of fish testing by invertebrate testing; however, we ask the Commission to provide further justification on the reliability, reproducibility and environmental relevance of the *Hyalella azteca* bioconcentration test (OECD TG 321). Furthermore, we note the limitations of the applicability domain, for example in case of low water solubility, and this should be addressed in Column 2. Introduction of OECD TG 319 (in vitro determination of intrinsic clearance from rainbow trout hepatocytes) as alternative for bioconcentration testing seems to be premature and not suitable for replacing the BCF for the environmental risk assessment and food chain accumulation.

Annex IX - Section 9.3.3 Adsorption/desorption

Commission proposal: none

NGO comment: Amend column 2 by removing the waiver based on low log Kow/ low potential for adsorption. The existing waiver for adsorption/desorption testing based on low log Kow/ low potential for adsorption should be deleted, as it counters the mobility assessment, as part of the PMT/vPvM identification.

Toxicokinetics / Absorption, distribution, metabolism and excretion (ADME) [Document CASG-IR-ED/07/2025]

Annex VII - Standard information requirements for toxicokinetics / absorption, distribution, metabolism and excretion assessment

Commission proposal: introduction of new section on toxicokinetics (TK) in Annex VII, including three in vitro assays for respectively protein binding, hepatic clearance, and intestinal absorption.

NGO comment: While we acknowledge that information on TK/ADME might be useful for grouping and read-across purposes, we believe that it is premature to include the suggested tests as standard information requirements in the REACH Annexes. The suggested tests do not have standardised and validated OECD test guidelines or applicability domains and test results vary considerably depending on the test conditions. Moreover, the use of the test results under REACH and CLP is unclear. Therefore, we suggest awaiting further discussion, test method development and validation among OECD experts, before introducing TK/ADME as standard information requirements under REACH.

We ask the Commission to clarify why only the uptake via intestinal absorption is covered in the proposal, while dermal absorption or uptake via respiratory tract cells or organs are not included in the test battery. This could lead to data gaps on the uptake of substances for which dermal or inhalation exposure are the major exposure routes. Furthermore, we wonder why metabolic capacity/metabolism is not included in the proposal.

In general, we caution against using data from a very limited test battery on TK/ADME to determine concentration ranges of in vitro tests required for (eco-)toxicological endpoints defined elsewhere in the REACH Annexes (e.g. endocrine disruption). The proposed approach to concentration setting would complicate the definition and evaluation of testing strategies by registrants and authorities, respectively, and move the assessment of the affected endpoints to a more risk-based approach which is not in line with the CLP regulation.

Conclusions and further recommendations

The standard information requirements for REACH registration dossiers are key to the identification of hazardous chemicals under the REACH and CLP regulation. Updating these requirements should enable an effective identification of critical hazards at all tonnage levels. We ask the Commission to provide further justifications underpinning the proposed changes, regarding reliability, reproducibility, and regulatory relevance of the proposed tests and demonstrating adequate protection of environment and human health. We also note the need for an overall EU Test method and validation strategy to ensure prioritisation, development and validation of tests that provide relevant information for classification under the CLP regulation, and SVHC identification and restriction under the REACH regulation.